Vertebral Body Balloon. For the reduction of fractures and/or creation of a void in cancellous bone in the spine.
# Table of Contents

## Introduction
- Vertebral Body Balloon 2
- AO Principles 3
- Indications and Contraindications 4

## Surgical Technique
- Patient Positioning 5
- Surgical Technique 6
- Access 8
- Determine Vertebral Body Balloon Size 11
- Prepare Inflation System 12
- Inflate Balloon 16
- Deflate and Remove Balloon 17
- Inject PMMA Bone Cement 18
- Postoperative Care 19

## Product Information
- Instruments 20
- Set List 23
Vertebral Body Balloon. For the reduction of fractures and/or creation of a void in cancellous bone in the spine.

Vertebral Body Balloon
- Three sizes to fit varying patient anatomy
- For the reduction of fractures and/or creation of a void in the cancellous bone in the spine

Inflation System
- Simple, easy-to-use inflation device
- Clear indication of volume and pressure during inflation

Vertebral Augmentation Access Kit
- Access options include guide wire and direct trocar approach
- Percutaneous, minimally invasive approach
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation. They are:
– Anatomic reduction
– Stable fixation
– Preservation of blood supply
– Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.

2. Ibid.
Indications and Contraindications

Indications
The Vertebral Body Balloon System is intended to be used for the reduction of fractures and/or creation of a void in the cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Contraindications
- Instability of posterior wall and/or pedicles
- Infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 75% of vertebral height is lost
- Any known severe allergy to contrast material
- Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon.

Please refer to the Vertebral Body Balloon package insert for complete system descriptions, indications, and warnings.
Patient Positioning

Position patient
Place the patient in the prone position on a radiolucent table to allow imaging of the targeted/affected levels.

AP and lateral fluoroscopy are used frequently throughout the procedure. Biplanar fluoroscopy is recommended for the most efficient use of imaging. A single, freely mobile C-arm may also be used. Use of a device that offers a high-quality image is required. Set up the table, patient and fluoroscopy to facilitate AP and lateral imaging throughout the procedure.
Surgical Technique

1
Approach

Instruments

| 03.804.512S | Vertebral Augmentation Access Kit |

The access instruments can be inserted through either a transpedicular or extrapedicular approach. Identify the anatomical landmarks of the affected segment(s) under imaging.

Option A: Transpedicular

Under fluoroscopy, determine the location of the incision. The incision should facilitate insertion directly through the pedicle.

**Important:** Do not breach the pedicle wall or anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the pedicle. Confirm the proper trajectory, then advance the instrumentation through the pedicle and into the vertebral body.

**Tip:** Ensure that the tip of the access instrumentation does not pass the medial wall of the pedicle in the AP view until it has passed the posterior wall of the vertebral body in the lateral view to avoid entering the spinal canal.

**Note:** If considering a transpedicular approach, ensure that the diameter of the pedicle is at least 5.9 mm to accommodate access instruments with an outer diameter of 4.7 mm.
Option B: Extrapedicular

Under fluoroscopy, determine the location of the incision. The trocar assembly should enter the vertebral body lateral to the pedicle.

Important: Do not breach the anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the posterolateral border of the vertebral body. Confirm the proper trajectory, and then advance the instrumentation into the vertebral body.
1

Determine access path
Access options include trocar or guide wire access. The trocar option allows access in a single step. The guide wire access can be used to create a path for the access instruments.

Option A: Trocar
To position the working sleeve, insert the access construct into the vertebral body in a single step.

Assemble the access construct, from the instrument assembly as provided in the kit (working sleeve, side-opening cannula and cannulated trocar). Replace the cannulated trocar with the trocar, and lock it into place with a clockwise rotation.

Under fluoroscopy, insert the access construct until the end of the working sleeve is positioned approximately 3 mm into the vertebral body. The end of the working sleeve can be viewed as a transition in diameter under fluoroscopy. For best visualization, temporarily slide the side-opening cannula partially out for fluoroscopic imaging. After imaging, slide the side-opening cannula fully forward into the working sleeve to adjust positioning of the access instrumentation as necessary.

If necessary, carefully hammer only on the metal pin of the trocar to gently advance the trocar instrumentation. Do not hammer on the plastic components.

**Important:** Ensure that the trocar instrumentation does not breach the anterior wall of the vertebral body.

Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy. Hold the working sleeve in place and carefully remove the trocar and the side-opening cannula, leaving the working sleeve in the vertebral body.

For bilateral procedures, repeat on the contralateral side.

**Warnings:**
Do not insert or advance the working sleeve in the bone without the side-opening cannula and trocar. This could damage the working sleeve and obstruct balloon insertion.

Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.
**Option B: Guide wire**

Insert the guide wire to create the access path, and position appropriately. Insert the instrument assembly of working sleeve, side-opening cannula and cannulated trocar over the guide wire and into the vertebral body.

- Under fluoroscopy, position the tip of the guide wire approximately 10 mm from the anterior wall of the vertebral body in the lateral view. The guide wires are marked with equidistant depth markers to allow monitoring of the insertion process. Monitor the guide wire position with fluoroscopy while inserting the instrument assembly of working sleeve, side-opening cannula and cannulated trocar over the guide wire, until the end of the working sleeve is positioned approximately 3 mm into the vertebral body. The end of the working sleeve can be viewed as a transition in diameter under fluoroscopy. For best visualization, temporarily slide the side-opening cannula partially out for fluoroscopic imaging. After imaging, slide the side-opening cannula fully forward into the working sleeve to adjust positioning of the access instrumentation as necessary. Ensure that the guide wire does not breach the anterior wall of the vertebral body.

**Important:** The guide wire will extend out the back of the handle. Advance the instruments carefully, to avoid injury to the physician's hand.

- Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy. Hold the working sleeve in place and carefully remove the guide wire, cannulated trocar and side-opening cannula, leaving the working sleeve in the vertebral body.

For bilateral procedures, repeat on the contralateral side.

**Warnings:**

- Do not insert or advance the working sleeve in the bone without the side-opening cannula. This could damage the working sleeve.

- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.

- Do not use excessive force on the guide wire to avoid potentially deforming the guide wire.
The plunger has two important uses:
- Create an access channel for balloon insertion
- Determine the appropriate balloon size

2

Create access channel

The access channel for the vertebral body balloon is created using the plunger.

Under lateral fluoroscopy, insert the plunger through the working sleeve and into the vertebral body. The plunger may be advanced by hand pressure or gently hammering on the protruding pin in the handle.

Optionally, the plunger can be removed at this point and the access channel created with the drill. Advance the drill slowly by turning on the handle clockwise.

Remove the drill and insert the plunger to size and verify balloon position.

Warnings:
Do not hammer on the drill.

Do not insert the drill or plunger beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.

Important: When inserting or removing the plunger or drill, ensure the working sleeve does not move.

For bilateral procedures, repeat on the contralateral side.
Determine Vertebral Body Balloon Size

The vertebral body balloon is available in three sizes: small, medium and large.

Vertebral Body Balloons, sterile

<table>
<thead>
<tr>
<th>Max. Dia. (Inflated) (mm)</th>
<th>Pre-Inflated Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.804.500S Small</td>
<td>15</td>
</tr>
<tr>
<td>03.804.501S Medium</td>
<td>17</td>
</tr>
<tr>
<td>03.804.502S Large</td>
<td>17</td>
</tr>
</tbody>
</table>

The pre-inflated length is the unexpanded balloon length.

Once the plunger has been positioned appropriately, use lateral fluoroscopy to determine the appropriate vertebral body balloon size. The plunger has three grooves near the distal tip that correspond to the three sizes:

**From distal tip, the first groove visible:**
Vertebral body balloon, small

**From distal tip, the second groove visible:**
Vertebral body balloon, medium

**From distal tip, the third groove visible:**
Vertebral body balloon, large

**Note:** If no plunger grooves are visible under fluoroscopy, adjust the working sleeve and/or the plunger if possible. If the instrumentation cannot be safely adjusted to reveal at least one groove, then the vertebral body balloon procedure will not be possible and an alternative augmentation procedure should be employed.

For bilateral procedures, repeat on the contralateral side.
Prepare Inflation System

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.804.413S</td>
<td>Inflation System</td>
</tr>
<tr>
<td>03.804.500S</td>
<td>Vertebral Body Balloon, small, sterile</td>
</tr>
<tr>
<td>03.804.501S</td>
<td>Vertebral Body Balloon, medium, sterile</td>
</tr>
<tr>
<td>03.804.502S</td>
<td>Vertebral Body Balloon, large, sterile</td>
</tr>
</tbody>
</table>

The following steps are required to prepare the inflation system and the vertebral body balloon:

1. Attach the stopcock to the inflation system
2. Fill the inflation system
3. Close the inflation system
4. Connect a balloon catheter to the inflation system and create a vacuum

For bilateral procedures, prepare two systems.

**Note:** The inflation system has an angled manometer that shows the pressure in the balloon in pounds/inch² (psi) and atmospheres (atm). The volume scale on the fluid chamber measures milliliters (ml).

Attach stopcock to inflation system

Attach the three-way stopcock to the inflation system tube via the Luer connector. The large arm of the stopcock knob (labeled “OFF”) always points to the channel that is closed. Position the stopcock knob so the lateral channel is closed.
1

**Fill the inflation system**
Prepare a contrast medium mixture with a ratio of contrast medium to saline solution of at least 1:2, and preferably 1:1.

**Notes:**
Check the patient for allergy to the contrast medium.

Follow the manufacturer’s recommendations for contrast medium use in the vertebral body.

Insert/connect the distal end of the stopcock to the contrast solution source. Slide the white wings on the sides of the inflation system forward while pulling back on the white handle to fill the chamber with fluid. Release the wings when the plunger bottoms out and the chamber is filled with fluid. With the handle pointing up, tap the unit to clear air out of the gauge portion of the inflation system.

Hold the inflation system with the handle facing downward. While pushing forward on the handle, rotate the handle clockwise to expel all the air in the barrel. Continue turning the handle clockwise, until solution starts to emerge and the leading edge of the red mark on the plunger reaches approximately 3 to 4 ml below the “0” mark, or until the red mark is aligned with the black line above the ml sign, beneath the “0” mark.

**Tip:** To make gross adjustments to the plunger, slide the wings forward to unlock the plunger.

2

**Close system**
Turn the stopcock knob to close the inflation tube channel.
3  
**Connect balloon catheter and create vacuum**
Remove the desired balloon from its packaging.

Slide the white cover sleeve covering the balloon toward the blue Luer connection and securely engage it to tip of the blue component.

Carefully remove the packaging wire from the catheter and discard.

Connect the vertebral body balloon to the three-way stopcock via the Luer connector.

**Note:** Ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

Turn the stopcock knob to close the lateral channel.

Slide the wings forward and pull the handle of the inflation system all the way back to pull the air out of the catheter, then release the wings while still holding the plunger back. This creates a vacuum in the catheter. The indicator on the manometer should point to “VAC.”
Turn the stopcock knob to close the catheter channel. This retains the vacuum in the balloon catheter.

Hold the inflation system with the handle facing downward and turn the handle clockwise, to set the volume scale to “0.” Turn the handle until the red ring on the plunger is precisely at “0.”

**Tip:** Suspend the three-way stopcock over a receptacle for all steps that involve expelling excess solution.

Turn the stopcock knob to close the lateral channel again.
Inflate Vertebral Body Balloon

Inflate balloons with fluid

The white sleeve aids in balloon insertion. Slide the white sleeve back over the balloon. While continuing to hold the white sleeve, use it to aid in balloon catheter insertion into the working sleeve under lateral radiographic control. After inserting the balloon catheter into the working cannula, carefully slide the white sleeve back toward the blue Luer connection and secure it in place. The full release (initial) length of the balloon is outside the working sleeve when the proximal end of the white portion of the catheter shaft disappears into the working sleeve. Check the position under radiographic control and confirm the desired position under AP view.

Note: If it is not possible to completely insert the balloon catheter so that the white portion of the catheter shaft disappears, it may be necessary to clear the path again using the plunger.

To inflate the balloon, slowly rotate the handle of the inflation system clockwise while monitoring the pressure and volume. Proceed with inflation slowly, stopping every few seconds to allow the bone to adjust to the pressure/volume changes. Use fluoroscopy to monitor balloon inflation.

Stop increasing pressure when any of the following happen:
– The desired clinical outcome is reached
– The pressure reaches 30 atm (440 psi)
– The maximum volume is achieved
  – 4.0 ml for the small balloon
  – 4.5 ml for the medium balloon
  – 5.0 ml for the large balloon

Important: The balloons may leak if they are filled beyond their maximum volume or pressure.

For bilateral procedures, inflate each balloon alternately in increments.

Notes:
For bilateral procedures, it is important to ensure balloon inflation does not induce misalignment. However, it may be desirable to inflate the balloons to different volumes to prevent or correct misalignment.

Each balloon is for single use only and should not be reinserted or inflated after the initial use.
Gradually decrease the pressure by turning the handle of the inflation system counterclockwise, until the manometer indicates approximately 10 atm (150 psi). Slide the wings forward while pulling the handle all the way back slowly, to fully collapse the balloon and draw a vacuum. Release the wings with the handle pulled all the way back, to seal the vacuum.

Hold the working sleeves in place and remove the catheters to retrieve the balloons.

**Note:** If the balloon does not deflate, check the connections to the inflation system, draw a vacuum again, or assemble a new inflation system to draw a vacuum and collapse the balloon.

**Important:** The balloon material is not implant-grade material. If balloon rupture occurs, visually inspect the ruptured balloon to confirm no fragment is missing from it. If any portion of the balloon is missing, it must be retrieved from the patient.

**Note:** If it becomes difficult to remove the balloon catheters through the working sleeves, twist the catheter while firmly pulling the catheter. If removal is still difficult, remove the balloon catheters together with the working sleeves, then re-access the vertebral body using the working sleeve with the side-opening cannula/trocar assembly. Once re-access is complete, remove the side-opening cannula/trocar assembly.

For bilateral procedures, deflate each balloon alternately in increments.
Inject PMMA Bone Cement

**Instrument**

| 03.804.512S | Vertebral Augmentation Access Kit |

Follow the manufacturers’ recommendations for PMMA use in the vertebral body.

Insert the injection cannula through the side-opening cannula and pivot clockwise to lock.

Insert the side-opening cannula construct into the working sleeve. Connect a PMMA delivery system via the Luer lock.

Under lateral fluoroscopy, inject PMMA cement. The direction of the PMMA flow can be changed by orienting the handle of the side-opening cannula to correspond to the direction of PMMA cement flow. The arrow on the handle of the side opening needle corresponds to the side of the opening. The PMMA should be contained within the vertebral body.

**Note:** If using a bilateral approach, simultaneously fill both sides in increments. It is important to see the filling behavior of both needles. Once the filling of one side is accomplished, the lateral view of the opposite side is hidden by the cement, which makes monitoring the flow more difficult.

**Warning:** Closely monitor the PMMA injection under fluoroscopy to reduce the risk of cement leakage. Severe leakage can cause death or paralysis. If cement leakage is observed during the procedure, STOP cement injection and consider: waiting for the cement already injected to harden, repositioning the needle, adjusting the needle direction, or stopping the procedure. If desired, continue cement injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease cement injection.
Once the cement has fully hardened per the manufacturer's instructions, remove the side-opening cannulas and working sleeves.

**Note:** If the working sleeves are removed before the cement is sufficiently hardened, there is risk of pulling cement fibers into the muscle tissue. If this happens, cement residue should be removed from the soft tissues.

Close wound.

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**Postoperative Care**

Place the patient in the supine position after surgery to compress the wound. Bruising may occur at the puncture sites. The patient may then be mobilized at the physician's discretion.
## Instruments

### Vertebral Body Balloons, sterile

<table>
<thead>
<tr>
<th></th>
<th>Pre-Inflated Length (mm)</th>
<th>Max. Dia. (Inflated) (mm)</th>
<th>Max. Volume (ml)</th>
<th>Max. Pressure (bar)</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.804.500S</td>
<td>Small</td>
<td>22</td>
<td>15</td>
<td>4.0</td>
</tr>
<tr>
<td>03.804.501S</td>
<td>Medium</td>
<td>27</td>
<td>17</td>
<td>4.5</td>
</tr>
<tr>
<td>03.804.502S</td>
<td>Large</td>
<td>31</td>
<td>17</td>
<td>5.0</td>
</tr>
</tbody>
</table>

![Pre-inflated length]

### Inflation System, sterile

03.804.413S       **Inflation System, sterile**

Contains:
1 Stopcock
1 Inflation device

![Inflation system diagram]
03.804.512S  Vertebral Augmentation Access Kit, sterile

Contains:

2 Cannulas with side opening, with Luer lock

2 Injection cannulas with Luer lock

2 Guide wires with depth markings

2 Trocars

2 Cannulated trocars

2 Vertebral augmentation access working sleeves

1 Vertebral augmentation access drill

1 Vertebral augmentation access plunger
Optional Implants and Instruments

07.702.010S  Vertecem Mixing Kit, sterile

Contains:
1 Vertecem Mixer with cement powder
1 Monomer glass ampoule

03.702.215S  Vertecem V+ Syringe Kit, sterile

Contains:
1 Stopcock
5 2cc Syringes, white plunger
8 1cc Syringes, blue plunger
## Vertebral Body Balloon Eval Set (01.804.610E)

<table>
<thead>
<tr>
<th>Carry Case</th>
<th>60.804.600</th>
<th>Carry Case, Vertebral Body Balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instruments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>03.702.215S</td>
<td>Vertecem V+ Syringe Kit, sterile</td>
<td></td>
</tr>
<tr>
<td>03.804.413S</td>
<td>Inflation System, 2 ea.</td>
<td></td>
</tr>
<tr>
<td>03.804.512S</td>
<td>Vertebral Augmentation Access Kit, sterile</td>
<td></td>
</tr>
<tr>
<td>03.804.500S</td>
<td>Vertebral Body Balloon, small, 2 ea.</td>
<td></td>
</tr>
<tr>
<td>03.804.501S</td>
<td>Vertebral Body Balloon, medium, 2 ea.</td>
<td></td>
</tr>
<tr>
<td>03.804.502S</td>
<td>Vertebral Body Balloon, large, 2 ea.</td>
<td></td>
</tr>
<tr>
<td><strong>Implants</strong></td>
<td></td>
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<tr>
<td>07.702.010S</td>
<td>Vertecem Mixing Kit, sterile</td>
<td></td>
</tr>
</tbody>
</table>

Note: For additional information, please refer to package insert. For detailed cleaning and sterilization instructions, please refer to http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed inserts, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices - Instruments, Instrument Trays and Graphic Cases—DJ1305
- Processing Non-sterile Synthes Implants—DJ1304